REMARKS

This responds to the Office Action mailed on October 27, 2005.

Claim 60 was amended; as a result, claims 1-58 and 60-63 are now pending in this application. The allowance of claims 1-58 and 52-63 is acknowledged.

In the Office Action, the Examiner maintained the rejections of claim 60 under 35 U.S.C. § 112, second paragraph, as indefinite and under 35 U.S.C. § 112, first paragraph, as broader than the enabling disclosure. These rejections are respectfully traversed.

As amended, pending claim 60 reads as follows:

60. A therapeutic method for treating a condition that utilizes bone marrow ablation followed by stem cell transplantation, with or without stem cells comprising an exogenous gene, in a mammal in need of such therapy comprising administering to the mammal an effective bone marrow ablating amount of a complex of claim 52.

The complex of claim 52 is a radionuclide-containing complex of claim 1. Both of these claims have been found allowable by the Examiner.

The Examiner cannot dispute that the claim preamble, "a condition that utilizes bone marrow ablation followed by stem cell transplantation" would be vague to one of ordinary skill in the art, or that one of ordinary skill in the art would be unaware of the conditions presently treated with bone marrow ablation, followed by stem cell transplantation. Although the Examiner has focused on the brief description at pages 6-7 of the specification, the disclosure of such conditions in the specification is much more extensive. The Examiner is referred to, and is urged to consider, the disclosure at pages 23-25 "Bone Marrow Transplantation and Restoration", as well as the material at pages 25-34 which details cancers, autoimmune diseases, infections and infectious diseases localized to the bone and other pathologies, such as hematopoietic genetic diseases, that are treatable with the present radionuclide complexes alone or in combination with

irradiation or other chemotherapy. Such treatments will necessarily "utilize bone marrow ablation", as recited by the claim and will be "treated with stem cell transplantation" as recited by the claim. Thus, it is respectfully submitted that it would be clear to one of skill in the art "what other condition[s] Applicant is referring to that [are] compatible with the instant invention [beyond] sickle cell anemia and lysosomal and peropisanal storage diseases".

With respect to the non-enablement rejection, there can be no question that the specification adequately and fully describes how to use the present complexes in regimens that involve bone marrow ablation, followed by stem cell transplantation. The Examiner asserts that claim 60 encompasses "a vast number of possible conditions". However, the Examiner provides no evidence to support this assertion and in fact, in paragraph 2, asserts that the "references of record do not indicate which specific conditions treatable with stem cell transplantation, with or without gene therapy, that utilize bone marrow ablation are useful with the claimed invention."

In the first place, breadth is not per se indefiniteness. Furthermore, Applicants dispute that the number of such conditions are "vast". The prior art patent, U.S. Patent No. 6,767,531 (of record), contains an extensive disclosure similar to that in the present application of just such conditions, at Cols. 13-21.

With respect to the claim element "with stem cells comprising an exogenous gene". The Examiner is requested to note that methods to practice such therapy, e.g. to produce and administer "transgenic stem cells" are disclosed in the specification at pages 34-36, along with conditions treatable with such cells. Applicants do not claim to have invented such "gene therapies" but are only claiming that it is reasonable that they could be used as a part of the restoration of the hematopoietic system, following bone marrow ablation with the present radionuclide complexes.

It is not Applicant's burden to prove, as asserted by the Examiner, "with certainty the end result described by Applicant" or " that all stem cell transplantation conditions are treated with the composition of the instant invention." The latter statement mischaracterizes the claimed invention. The claimed compositions act to abate the bone marrow, which then can be restored by any stem cell transplantation technique available to the art, many of which are detailed in the specification. The Examiner has provided absolutely no factual evidence to the contrary. The Examiner has only attacked the sufficiency of a few lines of the specification, and some of the

extrinsic evidence provided by Applicants, while ignoring many pages of relevant disclosure in the specification and in the '531 patent. Therefore, withdrawal of the rejections is appropriate and is respectfully requested.

CONCLUSION

The amendment to claim 60 was made to improve its clarity and does not raise issues requiring further search or consideration. Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6903 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 21st day of December, 2005.

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